

REMARKS

Claims 12-32 are pending in this action. According to the Office Action of September 7, 2007, all pending claims have been rejected. By this Amendment, Applicants have cancelled claims 12, 14, 30 and 31, have amended claims 13, 24-29 and 32, and have added a new claim 33. No new matter has been added by this Amendment.

On page 2, the Office Action contends that, "should claim 12 be found allowable, claim 29 will be objected to under 37 C.F.R. 1.75 as being a substantial duplicate thereof." Claim 12 has been cancelled, and claim 29 has been amended to depend from claim 28, which does not recite the "liquid" limitation. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 13-23 and 30-32 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Particularly, the claims were rejected for the recitation of "having a reduced digestibility of less than 30% of the digestibility of native starch." Applicants respectfully traverse this rejection because, as evidenced by the Minekus *et al.* reference ["A multi-compartmental dynamic computer controlled model simulating the stomach and small intestine" ATLA 23(1995): 197-209], a copy of which is enclosed, the meaning of the term "native starch" is clear to a skilled artisan. Notwithstanding the above, Applicants have deleted this recitation from the claims without prejudice. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 12 and 25-32 have been rejected under 35 U.S.C. § 103 as purportedly being unpatentable over Kaufman (U.S. Pat. No. 5,605,893) in view of Heber *et al.* [J. of Am. College of Nutrition, 16(6): 608-614]. Applicants respectfully traverse this rejection because neither Kaufman nor Heber, viewed alone or in combination, teaches or suggests the claimed invention.

For a reference to obviate a claimed invention, it must either expressly, implicitly or inherently teach each and every element of the claimed invention. MPEP § 2112. "All words in a claim must be considered in judging the patentability of that claim against the prior

art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” MPEP § 2143.03. On page 4, the Office Action states that “the degree of branching is not seen to be a critical factor as discussed above; therefore, absent any evidence of criticality or unexpected results, the recited degrees of branching are obvious variants of the method taught by Kaufman.” Applicants respectfully request that the recitation of an α -glucan having a degree of branching of at least 8% be given proper consideration as required by MPEP §§ 2112 and 2143.03.

Moreover, as is evident from Example 3 in the Specification, the degree of branching is a critical factor. Pullulan, which has virtually no branching, is reported as having a relatively high absolute viscosity, but a negative viscosity change upon acidification, i.e. when passing from the food environment (e.g. pH 4) to the stomach environment (e.g. pH 2). Glycogen, which has a degree of branching of approximately 8-9%, has a low absolute viscosity and a very positive viscosity change upon acidification. Reuteran, which has a degree of branching of approximately 16%, has a moderately-high absolute-viscosity, and a positive viscosity change upon acidification. Thus, an increase in the degree of branching had a significant impact on the change in viscosity upon acidification.

In this case, neither Kaufman nor Heber teaches a food composition containing an α -glucan with branching of at least 8%. Kaufman uses corn starch, which contains amylopectin. As acknowledged on page 4 of the Office Action, Kaufman’s amylopectin has a degree of branching of 4-5%, which is well below the recited 8% degree of branching. Additionally, Kaufman teaches using corn starch. Although not expressly stated in Kaufman, the only way Kaufman’s food composition may induce satiety is by increasing blood glucose levels. In contrast, the claimed food composition does not rely on increasing blood glucose levels to cause satiety. Another distinction is that the corn starch taught by Kaufman is digestible, as is the amylopectin. In contrast, the claimed invention has a reduced digestibility.

Kaufman’s deficiency is not overcome by Heber. Heber is directed to weight loss using Ultra Slim-Fast®. Ultra Slim-Fast® does not contain an α -glucan having a degree of branching of at least 8%, nor does it provide any motivation to use highly-branched glucans.

Therefore, neither Kaufman nor Heber, individually or in combination with each other, teaches or suggests the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 13-23 have been rejected under 35 U.S.C. § 103 as purportedly being unpatentable over Kaufman in view of Okuno *et al.* [Diabetes Res. Clin. Pract. Dec. (1985) 1(4): 221-225] in further view of Barbier *et al.* (U.S. Publ. Pat. App. No. 2002/0035089).

The method recited in claims 13-23 is directed to a method of inducing satiety and satiation in a person in need thereof. The claimed method uses an α -glucan having a degree of branching of at least 8%. As discussed above, Kaufman does not teach the an α -glucan having a degree of branching of at least 8%, and, at best, teaches a food composition that induces satiety by increasing blood glucose levels, whereas the claimed invention produces satiety via a different mechanism. Okuno and Barbier likewise fail to teach the recited α -glucan. Moreover, the combination of the three references fail to provide any teaching, motivation or suggestion of using the recited α -glucan. Therefore, these references do not obviate the claimed method.

Additionally, Kaufman is not directed to weight management or inducing satiety because the food composition disclosed in Kaufman is directed to preventing hypoglycemia in diabetic patients by diminishing fluctuations in blood sugar, whereas the method recited in claims 13-23 is directed to inducing satiety without increasing caloric intake. Therefore, by using the claimed method, one could reduce his or her caloric intake, which is not the case with Kaufman's food composition.

Consequently, there is no motivation to combine Kaufman with Okuno and Barbier. A rejection under Section 103 must be supported by some reason for a skilled artisan to combine the elements in the same manner as the applicant. *KSR Int'l v. Teleflex*, 82 U.S.P.Q.2d 1385, 1397 (U.S. 2007). The reason or motivation cited cannot be based on hindsight. MPEP § 2145. Combining Kaufman with Okuno does not motivate a skilled artisan to develop the claimed invention. As discussed above, Kaufman is directed to a food composition that provides calories. Okuno associates hypoglycemia with hunger. Combining these two references would lead a skilled artisan to conclude that a person becomes hungry because his or her blood sugar levels are reduced; therefore, by increasing blood sugar levels, the hunger can be satisfied. The fact that Okuno describes hunger as a symptom of hypoglycemia is irrelevant to the question of whether Kaufman teaches any portion of the claimed invention, which induces satiation via different mechanisms.

There is no motivation to combine Barbier with Kaufman or Okuno because Barbier is directed to a completely different issue. Barbier is directed to controlling obesity by administering a lipase inhibitor thereby inhibiting the breakdown of fats, whereas the other references are directed to treating hypoglycemia via increasing and/or stabilizing blood sugar levels. A skilled artisan would not be motivated to combine these teachings due to the different issues that they address.

In addition to the lack of motivation, the claimed invention is patentable over the cited references even if they are combinable because the claimed invention uses a different mechanism to induce satiety. Assuming that Kaufman teaches satiating hunger, Kaufman induces satiety by increasing blood glucose levels. Okuno merely notes that hunger occurs under hypoglycemic conditions. Barbier is directed to a method of inhibiting the breakdown of fats, and does not induce satiety. The starch or starch derivative used in Barbier for sequestering bile acids (which aid in the digestion of fats) reduces fat digestion. Barbier's starch is not a highly branched α -glucan as recited in the claims. In fact, Barbier teaches away from the claimed invention because it teaches controlling the digestion of fats, not providing food compositions with reduced digestibility.

These approaches differ substantially from the claimed invention, which utilizes an α -glucan having a degree of branching of at least 8%. For a reference to make obvious a claimed invention, it must either expressly, implicitly or inherently teach each and every element of the claimed invention. MPEP § 2112. “‘All words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” MPEP § 2143.03. At page 6, the Office Action asserts that “the degree of branching and method of preparation of the α -glucan is not seen to be a critical factor. The instant method utilizes α -glucan as a material in the method. Unless the process of preparing the α -glucan changes its structure, then it does not further limit the instant invention.” Applicants respectfully request that that the recitation of an α -glucan having a degree of branching of at least 8% be given proper consideration as required by MPEP §§ 2112 and 2143.03.

As recited in Claim 23, the claimed invention is directed to food compositions that do not have an excessive viscosity effect, but, after arrival in the digestive tract, especially

compositions, whereas the cited prior art is not. There is no basis for assuming that amylopectin, which has a lower degree of branching, has a stronger viscosity-increasing effect. In fact, as evident from the results of pullulan recited in the Specification, amylopectin does not have a stronger viscosity-increasing effect. Moreover, unlike the claimed invention, amylopectin is digestable, and therefore would increase caloric intake instead of reducing it.

Thus, even assuming that the cited references are combinable, none of the cited references teaches a method of satiating hunger by administering the recited α -glucan.

Accordingly, Kaufman, Okuno and Barbier, viewed individually or in combination with each other, do not teach or suggest the claimed invention. As such, reconsideration and withdrawal of this rejection are respectfully requested.

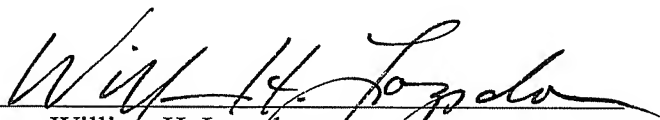
Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims in the instant application are patentable over the prior art and are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections and objections, and a notice of allowance are respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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